



UNITED STATES PATENT AND TRADEMARK OFFICE

ch
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,986	11/02/2004	Fareed Kureshy	100788.0009US	2956
<div>34284 7590 06/13/2007</div> <div>Rutan & Tucker, LLP. Hani Z. Sayed 611 ANTON BLVD SUITE 1400 COSTA MESA, CA 92626</div>				
<div>EXAMINER</div> <div>OWENS, GARRISON A</div>				
<div>ART UNIT PAPER NUMBER</div> <div>1609</div>				
<div>MAIL DATE DELIVERY MODE</div> <div>06/13/2007 PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,986

Applicant(s)

KURESHY ET AL.

Examiner

Garrison Owens

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1609

Detailed Action

1. Claims 1-20 are pending. Claims 11-20 are withdrawn from consideration.

Claims 1-10 are examined.

Election/Restriction

2. Applicants' election of Group I, claims 1-10, without traverse in the reply filed on 15 March 2007, is acknowledged. Restriction is deemed proper and is made final.

3. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Priority

4. This application claims the benefit of U.S. provisional patent application with the serial number 60/383,896, filed May 28, 2002, and international patent application with the serial number PCT/US02/17006, filed May 29, 2002. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365(c) as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

Art Unit: 1609

application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/383,896 and Application PCT/US02/17006 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The Examiner fails to find adequate support or enablement for the second energy source, and second energy detector. *Accordingly, claim 1 and all claims depending from claim 1 are not entitled to the benefit of the prior application.*

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 1-10** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **Claim 1**, and its dependent claims, are indefinite because claim 1 fails to clearly establish the metes and bounds of the invention. It is unclear to the Examiner the nature of the "coupling" in this claim. For example, it is unclear to the Examiner if the term relates to a "structural coupling" or to an "operational coupling", or if it is a "direct" or "indirect" coupling.

Art Unit: 1609

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship of the second energy source to the second energy detector.

Claim Rejections – 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1609

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims **1-3, 5-10** are rejected under 35USC 103(a) as being unpatentable over Kureshy et al., US Patent 5,141,871, (25 August 1992) in view of Sakka et al., US Patent 5,271,902, (21 December 1993).

The claims are drawn to an analytical device with an automatic pipette, comprising: a pipette tip receiving element coupled to a mechanism that translates the pipette tip receiving element along at least two of an x-coordinate, a y-coordinate, and a z-coordinate; wherein the pipette tip receiving element is further operationally coupled to a sensor that detects presence of a disposable polymer pipette tip that is removably coupled to the pipette tip receiving element; a first optical energy source and a first optical energy detector coupled to the pipette tip receiving element wherein the first optical energy source provides a first optical energy to a volume that is enclosed by the pipette tip, and wherein first energy detector receives at least a portion of the first optical energy from the volume; a second energy source and a second energy detector coupled to the pipette tip receiving element wherein the second energy source provides a second energy to a surface of a biochip when the pipette tip approaches the surface of the biochip; and a processor electronically coupled to the first and second energy detectors, wherein the processor controls accurate aspiration of a predetermined volume using a signal from the first detector, and wherein the processor controls

Art Unit: 1609

movement of the pipette tip along a z-coordinate using a signal from the second detector; and variations thereof.

For **claim 1**, Kureshy et al., teach in the abstract and in column 4, lines 5-9, an analytical device with an automatic pipette, (shown in Figure 1 as elements 40/42). Furthermore, the pipette receiving element (element 44 of Fig 1) is coupled to a mechanism (element 64, Figure 2) that translates the pipette tip receiving element in at least two dimensions (see column 4, lines 8-9; lines 17, 21 wherein the transport mechanism (element 64) provides for relative movement in two dimensions).

Kureshy et al., teach another embodiment of claim 1 wherein the pipette tip receiving element is further operationally coupled to a sensor that detects the presence of a disposable polymer pipette (see column 1, lines 45-46; column 5, lines 55-56; column 10, lines 3-9, see also, Figure 5, and Figure 6 such that the presence of the tip interrupts the light beam (first optical energy source which is signaled to the microprocessor) that is removably coupled to the pipette tip receiving element.

Kureshy et al., (see column 12, lines 28-35) teach a second energy detector coupled to the pipette tip receiving element wherein the second energy source provides a second energy to a surface of a biochip when the pipette tip approaches the surface of the biochip.

Kureshy et al., teach in column 4, lines 56-59; and column 5, lines 15-17, the optical detection system signals when the tip of the pipette (attached to the pipette receiving element) has advanced in the downward direction to a predetermined distance from a selected compartment of the cartridge (e.g., a biochip).

For **claim 2**, Kureshy et al, teach (see column 7, lines 31-33) the analytic device of claim 1 wherein the first energy source comprises a laser, and wherein the first energy is provided to the volume via a light guide (the light beam is applied to a tip containing a volume to be dispensed thus the light is also applied to the volume).

For **claim 3**, Kureshy et al,(see Figure 2, element 128; and Figure 7) teach the accurate aspiration is calculated from a reflected light signal that is detected by the first energy detector. It is the signal generated by reflection of light as the pipette tip crosses the light beam to the energy detector that begins the aspiration and dispensing step.

For **claim 5**, Kureshy et al., teach (see column 5, lines 21-24) an optoelectronic sensor.

For **claim 7** Kureshy et al., teach (see Figure 2, element 74) a robotic arm that translates the pipette tip receiving element along the x-coordinate, the y-coordinate, and the z-coordinate.

For **claim 8**, Kureshy et al, teach (see element 146, Fig 4) a data transfer interface.

For **claim 9**, the transfer of data to a person other than the operator is a recitation of an intended use of the claimed invention. This intended use of claimed

Art Unit: 1609

apparatus, as recited in claim 9, does not result in a structural difference between the claimed apparatus and the prior art of Kureshy, and does not patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

For **claim 10**, Kureshy et al, teach a sample station (see Fig 2, element 68) with a multi-well plate and a multi-reagent pack (see Figure 2, element 66), wherein the pipette tip removes a fluid from at least one of the multi-well plate and the multi-reagent pack and dispenses the fluid onto the surface of the biochip.

The prior art teachings of Kureshy et al., differ from the claimed invention as follows:

Kureshy et al., fail to teach in **claim 1**, a first optical energy source and a first optical energy detector coupled to the pipette tip receiving element wherein the first optical energy source provides a first optical energy to a volume that is enclosed by the pipette tip, and, wherein first energy detector receives at least a portion of the first optical energy from the volume.

Kurshey et al., also fail to teach a processor electronically coupled to the first and second energy detectors, wherein the processor controls the accurate aspiration of a predetermined volume using a signal from the first detector, and wherein the processor controls movement of the pipette tip along a z-coordinate using a signal from the second detector.

Art Unit: 1609

For **claim 6**, Kureshy et al., also fail to teach the disposable tip has a volume of equal or less than 200 microliter.

For **claim 4**, Kureshy et al., fail to teach the second energy source comprises an ultrasound transducer.

However, Sakka, et al., remedies the deficiencies of Kureshy et al., as follows:

For **claim 1**, Sakka et al., (see column 5, lines 8-22) teach a first optical energy source and a first optical energy detector coupled to the pipette tip receiving element wherein the first optical energy source provides a first optical energy to a volume that is enclosed by the pipette tip, and wherein first energy detector receives at least a portion of the first optical energy from the volume;

Sakka et al., (see column 7, lines 47-55) teach a processor electronically coupled to the first and second energy detectors, wherein the processor controls accurate aspiration of a predetermined volume using a signal from the first detector, and wherein the processor controls movement of the pipette tip along a z-coordinate using a signal from the second detector.

For **claim 6**, Sakka et al., teach (see column 6, lines 38-41), the pipette tip has a volume of equal or less than 200 microliter (invention is effective in taking out quantitatively a sample in small amounts, particularly from 1 to 150 microliter).

Art Unit: 1609

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the energy source and detection systems and a way of aspirating and dispensing an accurate volume of fluid taught by Sakka et al.

A person of ordinary skill in the art would have been motivated to combine the first energy source and the first energy detector coupled to the pipette tip receiving element creating a liquid level detecting device with Kureshy et al., because the liquid level detecting device of Sakka, et al., provides a device that is capable of detection at higher sensitivity in comparison with the more traditional type of devices. Also, the liquid detection system of Sakka provides a way to simultaneously and rapidly conduct liquid level detection and liquid sample suction of a micro-quantity of liquid without cross-contamination of the sample.

Finally, a person of ordinary skill in the art would have had a reasonable expectation of success because utilizing the system described by Sakka et al., because it has well known, robust elements for reliably detecting and quantifying a fluid volume and dispensing the fluid appropriately.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kureshy et al., US Patent 5,141,871 and Sakka et al., US Patent 5,271,902, (21 December

Art Unit: 1609

1993), as applied to claims **1-3 and 5-10** above, and further in view of Laugharn, Jr., et al., US Patent 6,948,843 (27 September 2005).

For **claim 4**, Laugharn, Jr., teach in column 2, line 42, the second energy source (acoustic energy source) e.g. such as an ultrasound transducer.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the energy source and detection systems and a way of aspirating and dispensing an accurate volume of fluid and a way of mixing the fluid sample taught by Laugharn, Jr., et al

A person of ordinary skill in the art would have been motivated to combine and modify the analytical instrument of Kureshy et al., to include an ultrasound transducer taught by Laugharn, Jr., et al., because the ultrasound transducer provides a way of mixing the sample. Mixing a sample with small volumes like the ones taught by the claimed invention helps to insure accurate distribution of the sample and this provides a more uniform uptake of the sample. By modifying the invention of Kureshy in this manner, this meets the requirement of Kureshy et al., to ensure that an accurate fluid volume is dispensed into an assay cartridge (e.g., a biochip) of a predetermined size range. Also mixing the samples before aspirating and dispensing provides another

Art Unit: 1609

mechanism to ensure accuracy of the volume in fluid uptake because it minimizes air bubbles present. This also provides for an even distribution of the fluid sample for uptake, which at very low volumes is crucial for accuracy. Minimizing the presence of air bubbles in a sample also helps to increase the reflection of energy transmission. Interfaces between air and water for example, result in efficient reflection of an incident ultrasound field.

Furthermore, one final example of an advantage of this system is no direct contact of the fluid to be mixed and the sonic energy source is required. This combination allows for a more accurate determination of the fluid volume to be dispensed in a very small area of the cartridge thus providing a basis for improving an area where complications have been previously encountered.

Finally, a person of ordinary skill in the art would have had a reasonable expectation of success because utilizing the system described by Laugharn, Jr., et al., because it has well known, robust elements for reliably non-contact mixing a fluid sample.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

Art Unit: 1609

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. **Claims 1-3, 5-10** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 5,141,871 in view of Sakka et al., US Patent No. 5,271,902 and Laugharn, Jr., et al., US Patent 6,948,843 (27 September 2005).

For **claim 1**, Kureshy et al., US Patent 5,141,871 claim analytical device with an automatic pipette, comprising: a pipette tip receiving element coupled to a mechanism that translates the pipette tip receiving element; wherein the pipette tip receiving element is further operationally coupled to a sensor that detects presence of a disposable polymer pipette tip that is removably coupled to the pipette tip receiving element; an energy source and an energy detector coupled to the pipette tip receiving element wherein the energy source provides energy to a surface of an assay element (e.g. a biochip) when the pipette tip approaches the surface of the assay element; and a

Art Unit: 1609

processor electronically coupled to the energy detector, and wherein the processor controls movement of the pipette tip using a signal from the second detector; and variations thereof.

US Patent 5,141,871 claims:

6. An analytical instrument in combination with a reservoir storing a fluid and employing a pipette for dispensing the fluid to an assay element, the instrument comprising:

a pipette and a supply of disposable pipette tips to be affixed to a stem of the pipette;

a conveyor for carrying an assay element;

transport means for advancing the pipette to said supply of disposable pipette tips for replenishment of a tip, the transport means advancing the pipette between the reservoir and an assay element for dispensing the fluid; and

wherein the analytical instrument further comprises an optical detection system which provides a light beam at a predetermined position relative to said conveyor for sensing the location of said pipette tip, the detection system providing a location signal indicating the presence of said tip at a reference location on a path of travel of the tip toward an assay element, the reference location being distant from the assay element; and

said transport means moving said pipette to the reference location, said instrument including means responsive to the location signal for computing an additional distance of travel based on the height of an assay element above a reference surface of said conveyor and for advancing said pipette tip from said reference location by said additional distance for placing said tip in a position for dispensing the fluid to an assay element.

7. An analytical instrument according to claim 6 wherein

said transport means in moving said pipette beyond said reference location to a second reference location on said travel path in the absence of an interruption of said light beam; and

said means responsive to said location signal is further responsive to the location of said pipette on said travel path for signaling the absence of said tip on said stem upon the attainment

However, Kureshy et al., US Patent 5,141,871, fail to claim the disposable tip to hold a volume of equal or less than 200 microliter.

However, Sakka, et al., remedies the deficiencies of Kureshy et al., as follows:

For **claim 1**, Sakka et al, US Patent No. 5,271,902, in the same field of invention teach (see column 5, lines 8-22) teach a first optical energy source and a first optical energy detector coupled to the pipette tip receiving element wherein the first optical energy source provides a first optical energy to a volume that is enclosed by the pipette tip, and wherein first energy detector receives at least a portion of the first optical energy from the volume;

Sakka et al., (see column 7, lines 47-55) teach a processor electronically coupled to the first and second energy detectors, wherein the processor controls accurate aspiration of a predetermined volume using a signal from the first detector, and wherein the processor controls movement of the pipette tip along a z-coordinate using a signal from the second detector.

For **claim 6**, Sakka et al., teach (see column 6, lines 38-41), the pipette tip has a volume of equal or less than 200 microliter (invention is effective in taking out quantitatively a sample in small amounts, particularly from 1 to 150 microliter).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the energy source and detection systems and a way of aspirating and dispensing an accurate volume of fluid taught by Sakka et al.

Art Unit: 1609

A person of ordinary skill in the art would have been motivated to combine the first energy source and the first energy detector coupled to the pipette tip receiving element creating a liquid level detecting device with Kureshy et al., because provides a way to gain a more accurate way of determining a volume to be aspirated or dispensed. Errors in quantifying the amount of such a small fluid volume (where the volume is equal to or less than 200 microliter) can result in drastic inconsistencies in assay results and experimental outcomes.

Finally, a person of ordinary skill in the art would have had a reasonable expectation of success because utilizing the system described by Sakka et al., because it has well known, robust elements for reliably detecting and quantifying a fluid volume and dispensing the fluid appropriately.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Garrison Owens whose telephone number is 571-270-3060. The examiner can normally be reached on Monday - Thursday, 7:30AM - 5PM, ALT. Friday, EST.

Art Unit: 1609

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GAO


MARK L. SHIBUYA
PRIMARY EXAMINER